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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,860	05/19/2000	CLAUDINE BRUCK	B45122	6653

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EXAMINER

NOLAN, PATRICK J

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/554,860

Applicant(s)

BRUCK ET AL.

Examiner

Patrick J. Nolan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2005 and 04 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 and 22 is/are pending in the application.
- 4a) Of the above claim(s) 8,9,11,14-17 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7,10,12,13 and 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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1. Claims 1-20 and 22 are pending.

2. Applicant's election with traverse of Group I, claims 1-16 and 18-20, and the species SEQ ID NO. 1 in the replies filed on March 7, 2005 and June 4, 2002 is acknowledged. The traversal is on the ground(s) that while the groups may be distinct, they are not independent because search terms for one group will necessarily be shared with other groups. This is not found persuasive because a search for protein products would not always overlap a search for treatment methods.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 8, 9, 11, 14-17 and 22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on June 4, 2002.

It is noted that SEQ ID NO. 1 in the current sequence listing is a nucleic acid, the Examiner performed a search on the protein encoded by said nucleic acid, SEQ ID NO. 2. In a review of the search, claims 2-7 and 10 were included in the examination as they were all encompassed by one prior art document. Claims 8, 9, 14-16 are withdrawn as being drawn to a non-elected species.

4. In a review of the specification, Applicant does not have consistent SEQ ID NOS, for all of the following, the CRF, the Figures, the specification, the drawings and the claims. Applicant is required to amend the specification, as needed, for the insertion of all the appropriate SEQ ID NOS, as they are recited in the CRF and Paper Copy, and amend the claims accordingly.

5. Applicant is required to insert the 35 USC 371 data either on the first page of the specification, or in an Application Data Sheet.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Forster et al.

Forster et al., teaches a recombinant mutant allergenic enzyme, that has decreased enzymatic activity as compared to the wild type allergen (see Methods, in particular).

The prior art teachings anticipate the claimed invention.

8. Claims 1 and 18 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent 6,287,559.

The '559 patent teaches pharmaceutical compositions of vespid allergen mutants with adjuvants for treating allergy to stings (claims 1, 7-8 and columns 17-23, in particular). While the claimed functional limitations, i.e. reduced enzymatic activity, is not recognized, the structural limitations have been met, and the burden is on Applicant to demonstrate the patentable differences, see MPEP 2112. It is further noted that for purposes of art, a pharmaceutical composition is found to be equivalent to a vaccine.

The prior art teachings anticipate the claimed invention.

9. Claims 1-7, 10 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Robinson et al.

Robinson et al., specifically teaches the cloned sequence to Der p 1, wherein the enzymatic activity of said sequence should be altered to test for the active site of said allergen. They specifically teach making the exact substitution encompassed by SEQ ID NO. 2 (claims 1-6 and 13) and by claim 7, (see page 18, 2nd column, in particular).

The prior art teachings anticipate the claimed invention.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1 and 18-20 rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,287,559, in view of US Patent No. 5,762,943.

The '559 patent has been discussed supra.

The claimed invention recited in claims 19 and 20 differs from the prior art teachings by the recitation of using 3D-MPL in the vaccine composition. However, the '943 patent teaches adding 3D-MPL (3D-MLA and 3D-MPL are the same) to an allergen preparation to prevent allergic reactions of the patient to the administered allergen and therefore make safer allergen immunotherapy (see column 2 in particular).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to add 3D-MPL to the allergen pharmaceutical composition taught by the '559 patent because it would make the allergen immunotherapy safer as recognized by the '943 patent.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 1-2 and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

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relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The scope of claim 1 is enormous. It is essential drawn to any and all allergens that are enzymes that have been mutated to lose enzymatic activity. The number of species encompassed by this genus is very large and growing as science isolated totally new and previously unrecognized allergens every day. Applicant's specification is limited to disclosing mutated variants from only one species, Der p 1, beyond this one species no other mutated proteins with reduced enzymatic activity are disclosed. A disclosure of only one protein from a genus of potentially hundreds if not thousands does not adequately describe Applicant's claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 is indefinite because it recites a protein, but recites a nucleic acid sequence to describe the protein. Correction is required.

13. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Nolan whose telephone number is 571-272-0847.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.

A handwritten signature in black ink, appearing to read 'Patrick J. Nolan'.

Patrick J. Nolan, Ph.D.

Primary Examiner, Group 1640

May 30, 2005